

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

19MB

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**21 CFR Part 524**

**Ophthalmic and Topical Dosage Form New Animal Drugs; Enrofloxacin, Silver Sulfadiazine Emulsion**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Bayer Corp., Agriculture Division, Animal Health. The NADA provides for veterinary prescription use of an enrofloxacin/silver sulfadiazine otic emulsion to treat otitis externa in dogs.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

**SUPPLEMENTARY INFORMATION:** Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141-176 that provides for veterinary prescription use of BAYTRIL® (0.5 % enrofloxacin/1.0% silver sulfadiazine) Otic Emulsion for the treatment of otitis externa in dogs. The NADA is approved as of September 29, 2000, and the regulations are amended in 21 CFR 524 by adding new section 524.802 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning September 29, 2000, because the application contains substantial evidence of effectiveness of the drug involved, or any studies of animal safety, required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### **List of Subjects in 21 CFR Part 524**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

#### **PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 524 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 524.802 is added to read as follows:

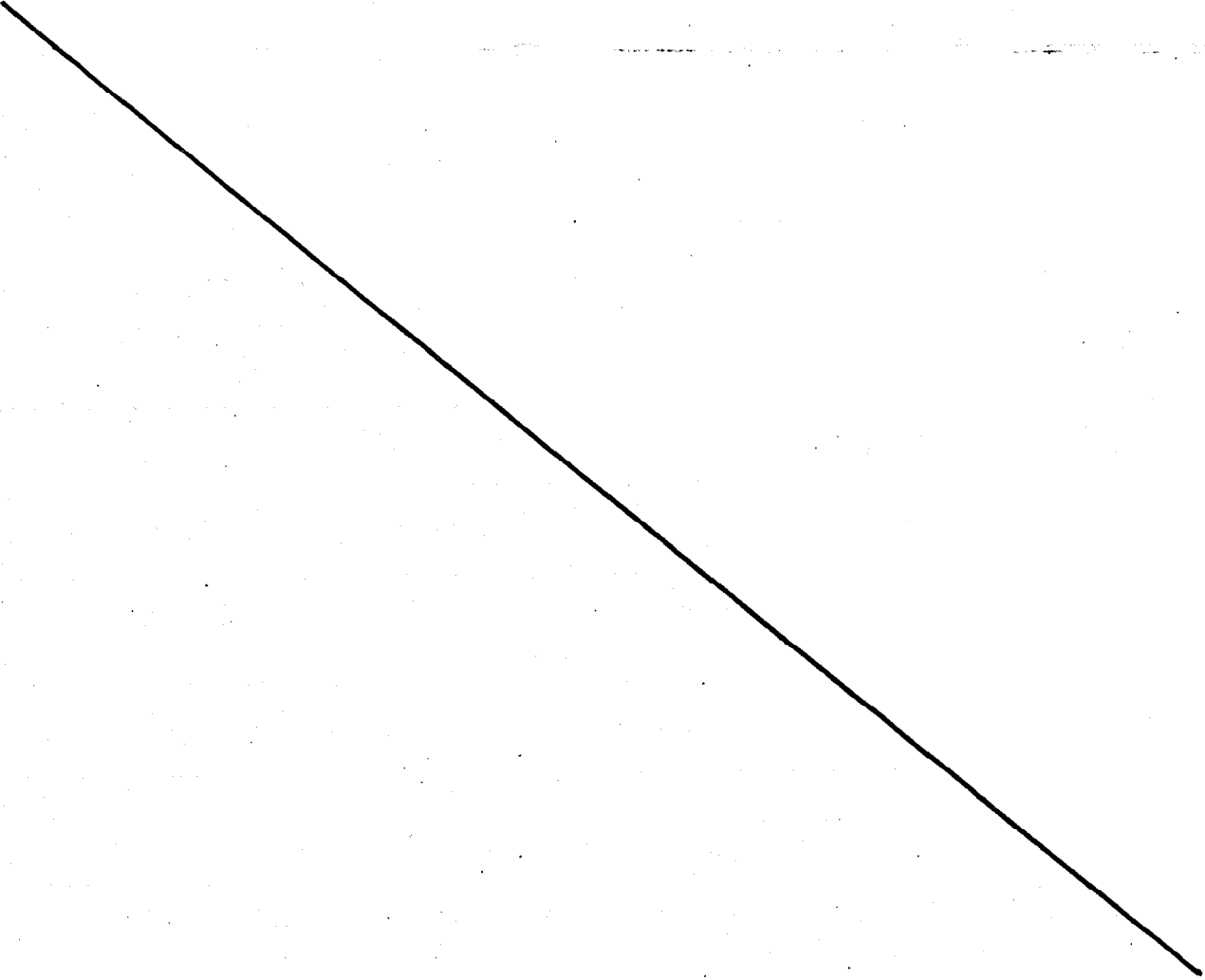
**§ 524.802 Enrofloxacin, silver sulfadiazine emulsion.**

(a) *Specifications.* Each milliliter contains 5 milligrams (mg) enrofloxacin and 10 mg silver sulfadiazine.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

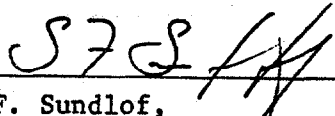
(c) *Conditions of use—Dogs—(1) Amount.* 5 to 10 drops for dogs weighing 35 pounds (lb) or less and 10 to 15 drops for dogs weighing more than 35 lb; applied twice daily for up to 14 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs.



(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

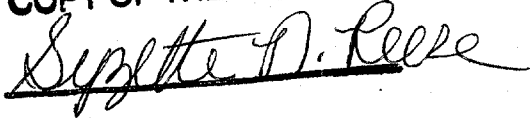
Dated: 10/26/00  
October 26, 2000.

  
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Stephen F. Sundlof,  
Director, Center for Veterinary Medicine.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Suzanne D. Reese